

BioMarker Solutions Group



IMPARTIALITY POLICY

Objectivity

“...not favouring one side over another”

Impartiality is one of the cornerstones of good ethics and company accreditation, as such it is of utmost importance in maintaining the trust of all our stakeholders. BMSG strongly adheres to ‘*The presence of objectivity*’, across all its operations and procedures it implements. Indeed, one of our Code of Conduct/Ethics, is to always maintain impartiality, and in all situations we confront.

BMSG is a for-profit group of companies, organised in such a way as to ensure that impartiality is not compromised by commercial, financial, or other pressures. BMSE does not engage in any activities which could compromise its impartiality; and expects that all suppliers, contractors, clients, partners and all other stakeholders it deals with abide by similar principles. BMSG applies its policies and procedures in a non-discriminatory way, and its services are available to all likewise minded and operational bodies, whether they be multi-nationals, SMEs, national or international organisations, or single individuals.

The impartiality and objectivity of the services that BMSG provides is tightly controlled. All BMSG personnel, contractors, and all other representatives of BMSG are required to declare any potential conflicts of interest. BMSG audits and accepts full regard of this information to ensure the objectivity of the services that it provides. Decisions within the group are not taken light-handedly and are made by competent persons with the freedom of independent thought, an ability to holistically assess the implications of their decisions by working as a team, and support BMSG considering any ramifications.

BMSE evaluates potential risks to its impartiality on an on-going basis using a number of mechanisms including internal audit, risk assessment, management review and consultation with appropriate interested parties. Where any such risks are identified, BMSE will implement appropriately monitored measures in order to eliminate or minimise them effectively.

In the event that customers or other stakeholders have concerns regarding the impartiality or objectivity of BMSG, BMSG has non-discriminatory procedures in place for the handling of complaints, adjudication and appeals thereof.

One of BMSG's challenges is in offering services, especially diagnostic testing with impartiality, and as such one overriding focus of adoption of ISO15189 is to align with ISO17025 in managing such, while risk assessing conflicts of interest within and external to the group.

There's pressure from clients, overbearing contractors, or even internal management for the "right" test results to be delivered in short periods of time. Situations of undue influence, conflicts of interest can lead to test results being either intentionally or unintentionally incorrect! If this is discovered after the results have been issued, it could not only be devastating to your business reputation but potentially have criminal implications. Therefore, we review, manage, educate and risk assess our procedures and processes considering the following with respect to impartiality.

Impartiality not only relates to our core activities in Diagnostics, but also across all spectrums of our activities from communications to production. The advice and examples of reducing/monitoring and/or mitigating impartiality are presented as examples for advice. All employees, contractors, anyone representing BMSG, anyone interacting with BMSG inclusive of all stakeholders that are considered to impinge upon our integrity and objectivity whether they be individuals, clients, supply chain, governments, technical assessors, or auditors need to complete our CDA and Conflict of Interest/Impartiality forms.

Advice

We offer some advice for our employee's, contractors or anyone representing BMSG's as part of this policy.

We implore our team to identify what situations could arise in the organisation and write them down. Think broadly and while many situations may seem unlikely it is still useful to get them out there in the open.

Threats to impartiality include the following:

Self-interest: threats that arise from a person or body acting in its own interest to benefit itself.

Self-review: threats arising from a person reviewing the work that they have conducted themselves.

Familiarity: threats that arise from a person being familiar with or trusting of another person.

Intimidation: threats that prevent one from acting objectively due to fear of another party.

Financial: the source of revenue.

Examples of Risks to impartiality:

- Diagnostic testing for compliance on an in-house product – what if the test result shows non-compliance, especially if the tester also has production responsibilities?
- Being given resources for testing, or an overbearing manager who just insists testing is under inappropriate circumstances.
- Being pressured to give a result, repeat the test, limit the test to an unsatisfactory methodology, perform it outside of our QMS (or indeed legal) parameters.
- Conflicts of interest due to shareholdings, family relationships, etc.
- Under-pricing jobs, putting time pressures on staff while expecting full processes to be completed.
- Details in contracts or requests for testing that present a risk to your laboratory: site selection; financial penalties for delays in TAT; methods specified not match the materials.

Now that these have been identified, see what can be done to reduce or eliminate these risks.

Ways to reduce impartiality effecting reliability of test results

Technology

- Direct capture of data in the facility – eliminating the risk of transcription errors.
- Directly logging data in the field into a tablet/ predefined table.
- Is automation an option? – Explore any possibilities, as they will likely improve you process efficiencies at the same time.

These steps don't necessarily need one of the off the shelf expensive software packages. Our in-house system (the Client System, and other

laboratory information and likewise activity-based information gathering tools) that captures relevant data and stores this in a secure way so there is no question on the integrity of the data is compliant with ISO27001 and the GDPR.

- Are there other technical advances in equipment that would allow for further automation that the industry could look at?
- Can BMSG be a leader in introducing this?
- What an opportunity!

Training and education

BMSG makes sure our staff know the implications of test results.

- What are the potential consequences of each different testing result if it ends up a FP or FN?
- What sensitivity and specificity criteria are essential to limit this?
- What is the minimum sensitivity cut-off for clinical relevance?
- Is the material appropriate; and if not?
- What if the technique, method of DNA extraction, or even a trusted device is not calibrated?

These and other factors are covered in training and in daily activities.

The implications of finding failure at this point are massive! If a failure is identified and dealt with immediately, any short-term pain dealing with someone who doesn't want the true result is negligible by comparison.

BMSG are advised and offered insight and voice of concern if they experience pressure to change results, and /or other less obvious pressures.

- Whom should they report this to?
- When should they stop and leave the site?

BMSG has formally incorporated appropriate policies into your training program to address these.

Organisational structure & reporting lines

BMSG has reviewed the structure of reporting lines: looking for potential conflicts of interest (such as results being used internally). This is common for production related organisations but also those involved in processes that are time limiting. Where possible, we aim to remove direct reporting lines such as the laboratory technician reporting to the laboratory manager. As we are a relatively small organisation, functions are covered by many individuals and there is a transparent approach to data and data confirmation within the relevant teams.

Checking the data

Independent reviews of results introduce a level of impartiality as well as the benefits of a fresh set of eyes for errors. BMSG realises that work is being done remotely on site, therefore there are steps in data recording that allow the whole team to trace data sets at any time, this ultimately reduces undue pressure on the team.

Contract review

Technical review of contracts is important. Many clients want to continuously minimise testing costs. In addition, there is mounting competition from unsolicited and less competent organisations

potentiating mistrust, and often a sense of unfair pricing amongst clients. Checking the technical, as well as financial details of the contract help make sure BMSG is not left out of pocket or pressured to complete inadequate testing.

Quality Culture

This comes from Senior Management, BMSG's Code of Conduct and Code of Ethics are clear on the type of culture this organisation portrays at all levels within and to all our stakeholders, a culture of openness, honesty and integrity goes a long way. We have policies in place to make sure employees know that they can speak up if they don't feel something is right, without the worry of some form of repercussion. No specific system can cover this, it is something that needs to be lived and breathed through the organisation at all levels. Having a quality system that is integrated with the day-to-day work is an important part of this: encouraging non-conformances to be raised or renaming them to reflect a positive change approach can help; highlighting the benefits of processes such as internal audits are just some examples of how you can help instil a culture of quality within BMSG.

BMSG Policy

BMSG through this policy, identifies, analyses and documents (using our policies and procedures) all possibilities for conflict of interests that may arise from any aspect in the performance of its activities, certification/ assessment processes, and any conflicts that arise from its relationships on an ongoing basis.

Relationships do not necessarily present BMSG with a conflict of interests. However, should any relationship create a threat to impartiality, BMSG shall document and eliminate or minimise any such threats and document any residual risk. Any residual risk identified shall be reviewed periodically to determine if it is within acceptable levels of risk. This information is presented to the Managing Director and the Management Team members.

It is necessary to cover all potential sources of possible conflict of interests. Sources that are identified regardless of their origin. BMSG shall use this information as an input in identifying threats to impartiality raised by the activities of such personnel or by the organisation that employ them. Such personnel, internal or external shall not be used unless they demonstrate that there is no conflict of interest. BMSG will not undertake any action that threatens the impartiality and/or are potential conflict of interest. BMSG employees, internal and external, shall comply with this procedure as well as reveal any situation known to them that may present themselves or BMSG with a conflict of interests.

BMSG hereby confirms implementation and adherence to the following:

- BMSG will ensure that our services shall be applied in a manner necessary to preserve impartiality, objectivity, independence, freedom from conflict of interest, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, and balance.
- BMSG does not receive any financial support different from that invested in it, and the fees of its services.
- BMSG does not pay any commissions to consultants, therefore, there can be no pressure exercised on BMSG by consultants.
- BMSG shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organisations.
- BMSG shall act impartially and shall not allow commercial, financial, or other pressures to compromise impartiality.
- BMSG shall only disclose reports, data, and documents with anonymized client data fields (PPI) to other sources; unless legally required to do so, having jurisdiction for the purpose of reporting compliance, or in conflicts of non-conformance; with clients written permission.
- BMSG shall base all its decisions on objective evidence obtained through effective processes based on objective evidence of conformity or nonconformity, risk-based assessments, managerial reviews, and that any decisions made are not influenced by other interests or by other parties; that

may damage the security or sustainability of BMSG. These assessments, together with certification/ accreditation and inspection decisions are made and approved by a competent person who is free from influence by other interests or parties, including those of BMSG's clients.

- BMSG's personnel will not be influenced by financial, commercial, or other pressures when conducting audits or reviews, and will take action to address any situation that would affect impartiality. Personnel are required to disclose any potential conflicts of interest at the earliest possible moment.
- BMSG shall not use personnel with an actual or potential conflict of interest and shall ensure that its personnel are free from commercial, financial, or other pressures that might affect their judgement.
- BMSG personnel taking part in audit, review, validation activities, both internal and external, shall act impartially when executing their responsibilities.
- BMSG undertakes to instil confidence in the delivery of its services to customers and parties that have an interest in its services and activities. This shall be achieved by upholding the principles of impartiality (including acting against threats, i.e., from self-interest, self-review, familiarity, intimidation), competence, responsibility, openness, confidentiality, and responsiveness to complaints.
- In the management of impartiality, BMSG recognises the possibilities for conflicts of interests arising from relationships of those persons or organisations having an interface with BMSG. This includes staff, sub-contractors, and licensees. Please also refer to the BMSG Conflict of Interest policy for further guidance.
- BMSG undertakes to complete a thorough assessment of the risks to impartiality and to determine the action to be taken to eliminate or minimise those risks. The risk assessment process will be on-going and will be maintained through BMSG's Executive and associated Management Review process.
- BMSG shall maintain up to date operating procedures including processes for appeals and will ensure that these procedures support impartiality.
- Occasionally BMSG is required to evaluate its systems, procedures and practices to ensure that impartiality in its activities are maintained. These are addressed through implementation of the risk assessment based QMS policies and procedures. Parties with an interest in BMSG are invited, by virtue of this policy, to submit any proposals, comments, or relevant observations on the services of BMSG, such that these may be considered by BMSG as part of its evaluation process for continual improvement.

Parties with an interest in BMSG include:

- BMSG Member Companies.
- BMSG Qualified Individuals.
- Clients of certified companies.
- Governmental Authorities.
- Non-Governmental organisations and trade bodies.
- Consumers and members of the public.

All comments may be addressed to the BOD.

- Consultancy organisations are an established part of the certification/accreditation implementation process. BMSG will co-operate with outside organisations for the benefit of its members but will have no direct affiliation with management/product system consultancy organisations. BMSG will take action to correct inappropriate claims of affiliation (stated or implied) by any consultancy or other organisation that suggests directly, or indirectly, that certification would be simpler, easier, faster or less expensive by virtue of their co-operation.
- BMSG shall enter into legally enforceable agreements with its clients yet retain all authority and responsibility for its activities, decisions and statements.
- BMSG shall elicit due diligence on all involved stakeholders with relevant assessment tools and clauses.
- BMSG's management system has the necessary procedures, safeguards, and tools to ensure that these policies are strictly upheld and enforced.

Definitions

- Impartiality means presence of objectivity.
- Conflict of Interest means a situation that has the potential to undermine the impartiality of a person because of the possibility of a clash between the person's self-interest and professional or public interest.
- Independence means freedom from the control, influence, support, aid, or the like, of others.
- Interested Party is a person or organization with a direct or indirect interest in BMSG (or its activities) including individuals, clients, supply chain, governments, technical assessors, or auditors.
- Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of BMSG.
- Transparency implies openness, communication, and accountability. It means operating in such a way that it is easy for others to see what actions are performed.